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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/583,521	ADUSUMILLI ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *217-242* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *217-242* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/09/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 217-242 are included in the prosecution.

Claim Objections

2. Claim 231 is objected to because of the following informalities: Claim 231 recites "…said carbonate radical precursor is present a compound different than that of said calcium salt". This should be corrected to recite: "said carbonate radical precursor is present as a compound …" Appropriate correction is required.

3. Claim 238 is objected to under 37 CFR 1.75(c) as being in improper form because it is dependent on claim 238 itself. See MPEP § 608.01(n). Claim 238 should be dependent on claim 228. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 221 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 221 recites that the carbonate radical precursor is "partially" replaced. It is unclear how much or what portion of the water soluble carbonate radical precursor is replaced.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 217-220, 222-239 and 241-242 are rejected under 35 U.S.C. 103(a) as being unpatentable over Puglia et al. (US 4,327,076) in view of Mitra (US 4,163,777).

The claimed invention is a pharmaceutical composition, comprising in admixture: an alginic acid or a salt thereof; a water-soluble carbonate radical precursor; a calcium salt; and a first bulk sweetener, wherein the composition is in powder form.

Puglia teaches the addition of a disintegrator, alginic acid, to a pre-tablet mix in order to produce a so-called “soft” tablet (Col. 2, lines 31-34). Alginic acid is also disclosed as a slip agent that is present in an amount from about 0.75 to about 1.5% based on the weight of the finished tablet (Col. 6, lines 10-18). Tablet bonders such as sugar and/or dextrose monohydrate are disclosed (Col. 3, lines 10-12). The total amount of bonders are present in the range of about 20 to about 60% by weight of the final composition (Col. 5, lines 32-39). Antacids such as calcium carbonate, aluminum hydroxide and/or magnesium hydroxide and binders such as carboxymethyl cellulose are disclosed (Col. 3, lines 13-24). The active ingredient or antacids are blended with the binder and the blend is compressed to form tablets (Col. 3, lines 51-63). Fat sorbing materials including cornstarch, sucrose, sorbitol, xylitol and mannitol are disclosed (Col. 4, lines 5-9). Example 1 discloses a tablet formulation with calcium carbonate,

aluminum hydroxide, magnesium hydroxide and carboxymethyl cellulose (Col. 7, line 44 to Col. 8, line 55).

Puglia does not expressly teach a water soluble carbonate radical precursor.

Mitra teaches an antacid delivery form and comprises an acid neutralization component in a matrix including a sugar or a sugar alcohol, a gel-forming, swelling agent and a water-insoluble lipid material (Col. 1, lines 5-15). The antacid delivery form continuously bathes the lining of the esophagus and provides relief for tissues inflamed by gastric reflux (Col. 1, lines 30-32). Illustrative antacids including sodium bicarbonate, calcium carbonate, magnesium hydroxide and aluminum hydroxide are disclosed (Col. 2, lines 38-42). Gel forming agents including alginic acid, cellulose derivatives such as methyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose and sodium carboxymethyl cellulose are disclosed (Col. 2, lines 53-68). The dosage forms are formulated from a granulation containing the antacid and a sweet tasting excipient (including sugar alcohols mannitol, sorbitol and xylitol), artificial sweeteners, and may also contain materials such as gelatin or starch or other materials such as talc (Col. 3, lines 8-38). The amount of the sweet excipient is 25 to 60 percent by weight of the delivery form and the amount of the gel forming swelling agent varies with the particular agents selected (Col. 3, lines 49-57). The wet granulation process is disclosed in Example 1 (Col. 4, line 55 to Col. 5, line 37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising alginic acid, bulk sweetener and calcium carbonate, as suggested by Puglia, combine it with the antacid delivery form

including a water soluble carbonate radical precursor such as sodium bicarbonate, as suggested by Mitra, and produce the instant invention.

One of ordinary skill in the art would do this because the water soluble carbonate radical precursors such as sodium bicarbonate are known to be used in antacid formulations, as evidenced by the teaching of Mitra (Col. 2, lines 38-42).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 217, the alginic acid would have been obvious over the alginic acid taught by Puglia (Col. 2, lines 31-34). The water soluble carbonate radical precursor would have been obvious over the sodium bicarbonate used in the antacid formulation taught by Mitra (Col. 2, lines 38-42). The calcium salt would have been obvious over the calcium carbonate taught by Puglia (Col. 3, lines 13-24) and by Mitra (Col. 2, lines 38-42). The first bulk sweetener would have been obvious over the sugar, dextrose monohydrate (Col. 3, lines 10-12) and the sorbitol, xylitol and mannitol (Col. 4, lines 5-9) taught by Puglia. The limitation of the composition in powder form would have been obvious over the dry blending of premixes I, II and II, as taught by Puglia (Col. 8, lines 40-42).

Regarding instant claim 218, the 70 to 500mg per unit dose of alginic acid per unit dose of the composition would have been obvious over the 0.75 to about 1.5% of alginic acid based on the weight of the finished tablet, as taught by Puglia (Col. 6, lines 10-18). One with ordinary skill in the art would modify the level of alginic acid in order to make the final composition or tablet softer, and impart the desirable chewable texture. The recited ranges of alginic acid amount would have been obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 219-220 and 231, the carbonate radical precursor would have been obvious over the sodium bicarbonate used in the antacid formulation taught by Mitra (Col. 2, lines 38-42).

Regarding instant claim 222, the recited range of the amount of carbonate radical precursor (from about 50 to about 200 mg per unit dose of the composition) would have been obvious variants to one with ordinary skill in the art because the level of carbonate radical precursor can be modified during the process of routine optimization, unless there is evidence of criticality or unexpected results.

Regarding instant claims 223-224, the calcium salt would have been obvious over the calcium carbonate taught by Puglia (Col. 3, lines 13-24) and by Mitra (Col. 2, lines 38-42).

Regarding instant claim 225, the recited range of the amount of calcium salt (from about 100 to about 1000 mg free calcium per unit dose of the composition) would have been obvious over the calcium carbonate used by Puglia (Example 1, Col. 7, line

44 to Col. 8, line 55). The recited ranges would have been obvious variants to one with ordinary skill in the art because the level of calcium salt can be modified during the process of routine optimization, unless there is evidence of criticality or unexpected results.

Regarding instant claims 226-227, the limitation of the composition further comprising the addition of magnesium or aluminum cation in the form of an antacid would have been obvious over the antacids such as aluminum hydroxide and/or magnesium hydroxide disclosed by Puglia (Col. 3, lines 13-24).

Regarding instant claims 228 and 233-234, the binding agent would have been obvious over the corn starch (Col. 4, lines 5-9), carboxymethyl cellulose (Col. 3, lines 13-24), sorbitol, xylitol and mannitol (Col. 4, lines 5-9) taught by Puglia.

Regarding instant claims 229 and 232, the first bulk sweetener would have been obvious over the sugar, dextrose monohydrate (Col. 3, lines 10-12) and the sorbitol, xylitol and mannitol (Col. 4, lines 5-9) taught by Puglia.

Regarding instant claim 230, the recited range of the first bulk sweetener (about 10% to about 30% w/w of a unit dose of the composition) would have been obvious over the total amount of bonders that are present in the range of about 20 to about 60% by weight of the final tablet, as taught by Puglia (Col. 5, lines 32-39). The limitation of wet granulation would have been obvious over the wet granulation taught by Mitra (Example 1, Col. 4, line 55 to Col. 5, line 37).

Regarding instant claim 235, the recited range of the amount of starch (an amount from about 1% to about 15% w/w) would have been obvious over the corn starch taught by Puglia (Col. 4, lines 5-9) because one with ordinary skill in the art can modify the level of corn starch during the process of routine optimization, unless there is evidence of criticality or unexpected results.

Regarding instant claims 236 and 241, the cellulosic derivative would have been obvious over the carboxymethyl cellulose (Col. 3, lines 13-24) taught by Puglia.

Regarding instant claim 237, the recited range of the cellulosic derivative would have been obvious over the carboxymethyl cellulose taught by Puglia (Col. 4, lines 5-9) because one with ordinary skill in the art can modify the level of cellulosic derivative during the process of routine optimization, unless there is evidence of criticality or unexpected results.

Regarding instant claims 238 and 242, the natural gum would have been obvious over the gelatin taught by Mitra (Col. 3, lines 8-38).

Regarding instant claim 239, the recited range of the natural gum (an amount from about 0.5% to about 7% w/w of the unit dose of the composition) would have been obvious over the gelatin taught by Mitra (Col. 3, lines 8-38) because one with ordinary skill in the art can modify the level of natural gum during the process of routine optimization, unless there is evidence of criticality or unexpected results.

8. Claims 221 and 240 are rejected under 35 U.S.C. 103(a) as being unpatentable over Puglia et al. (US 4,327,076) in view of Mitra (US 4,163,777) and Hermelin et al. (US 6,197,329).

The teachings of Puglia and Mitra are stated above.

Puglia and Mitra do not expressly teach replacing a portion of the water soluble carbonate radical precursor with sodium or potassium phosphate or a binding agent selected from the group consisting of Povidone, maltodextrin, a polaxamer, a polydextrose, polyethylene glycol, a polymethacrylate, and combinations thereof.

Hermelin teaches that sodium bicarbonate and sodium phosphate can be used as alkaline buffering agents (Col. 17, claim 10). Hermelin also teaches binders such as povidone and acrylic and methacrylic acid copolymers (Col. 13, lines 19-22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a chewable antacid tablet, as suggested by Puglia, combine it with the antacid delivery form including a water soluble carbonate radical precursor such as sodium bicarbonate, as suggested by Mitra, use sodium phosphate as an alternative alkaline buffering agent to replace a portion of the carbonate radical precursor, as suggested by Hermelin, and produce the instant invention.

One of ordinary skill in the art would do this because sodium bicarbonate and sodium phosphate are alkaline buffering agents known in the art (as evidenced by the teaching of Hermelin) and during the process of routine experimentation, one can replace the sodium bicarbonate with sodium phosphate.

Regarding instant claim 221, the limitation of partially replacing the carbonate radical precursor with sodium or potassium phosphate would have been obvious because sodium bicarbonate and sodium phosphate are alkaline buffering agents known in the art (as evidenced by the teaching of Hermelin - Col. 17, claim 10) and during the process of routine experimentation, one can replace the sodium bicarbonate with sodium phosphate.

Regarding instant claim 240, the limitation of the binding agent selected from the group consisting of povidone, maltodextrin, a polaxamer, a polydextrose, polyethylene glycol, a polymethacrylate, and combinations thereof would have been obvious over the binders such as povidone and acrylic and methacrylic acid copolymers taught by Hermelin (Col. 13, lines 19-22).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 217-242 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 78 and 217-306 of copending Application No. 10/888,242 (the '242 Application). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims as well as claims of the '242 Application are drawn to a pharmaceutical composition comprising in admixture: an alginic acid or a salt thereof; a water-soluble carbonate radical precursor; a calcium salt; and a first bulk sweetener. The difference is that claims of the '242 are drawn to a chewable tablet, while instant claims recite a powder composition. One of ordinary skill in the art would find it obvious to compress the powder composition of instant claims into a tablet formulation during the process of routine experimentation, and produce the invention of the '242 Application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615